VETERINARY BIOLOGICS

PROGRAM PROFILE

Goal	Prevent worthless, contaminated, dangerous, or harmful veterinary biologics from reaching consumers.
Enabling Legislation	21 USC 151-158 Virus-Serum-Toxin Act of March 14, 1913, and the Food Security Act amended December 23, 1985. Program began in 1924.
Economic Significance	APHIS protects the multi-billion dollar U.S. pet and livestock industries by preventing the production, distribution, and importation of worthless, contaminated, or harmful products. APHIS does this by regulating highly competitive industries that make use of rapid growth in microbiological techniques to develop a new array of sophisticated products. APHIS has the task of ensuring product safety and effectiveness without hindering development of beneficial products for American agriculture.
Principal approach and methods Used to Achieve Goals	Regulatory program that consists of licensing all products, inspecting licensed facilities, and testing samples of licensed products. Program requires veterinary biologics producers to be Federally licensed and meet Federal standards. Importation of veterinary biological products is regulated through issuance of permits. Supports APHIS program by ensuring that genetically engineered veterinary biologics are fully tested and comply with the National Environmental Policy Act prior to being released into environment. The Field Office at Ames, Iowa, conducts inspections of licensed establishments and products, and monitors product performance. The National Veterinary Services Laboratories (NVSL) conduct prelicense and check testing, develop new standard requirement tests, and provide references and reagents for standard requirement testing.
History	The program began in 1913. In 1945, veterinary biologics underwent a major change with development of live and modified live-virus vaccines. As a result, more vaccines and fewer serums and bacterium were produced. In 1985, the first license for a genetically engineered product, a pseudorabies vaccine, was issued. In 1986, APHIS received

authority to regulate producers who distribute veterinary biologics in intrastate commerce. APHIS regulations governing intrastate commerce in veterinary biologics are now in effect. Since 1986, APHIS has licensed three more recombinant DNA techniques that help us detect diseases like Johne's disease and chicken anemia.

State and Local Cooperation None

Involvement of Other Agencies Justice Department (prosecute violations); FDA (regulates medicines, drugs, and chemicals used to treat or cure animal diseases); NIH (public health aspects of veterinary biologics); and Customs Service (seizure of illegal imports).

RESOURCE DATA

	Obligations			
	Direct	Reimbursement	User Fees	Staff-Years
FY 1996	10,519,611	--	--	183
FY 1997	10,400,356	--	--	166
FY 1998	10,203,454	--	--	165
FY 1999 (est.)	10,345,000	--	--	161
FY 2000 (est.)	10,555,000	--	--	155

	APHIS	Coop	Total	CCC	Contingency Fund
Cum.	$245,690,283	--	$245,690,283	--	--

RECENT ACCOMPLISHMENTS

Licenses

In FY 1998, APHIS issued 141 product licenses, of which 14 were for products not previously available for use by veterinarians and animal owners for the diagnosis, prevention, or treatment of diseases in animals. The Agency also terminated 60 product licenses at the request of licensees for products no longer being produced as compared to 102 in FY 1997 and 94 in FY 1996. There were 2,446 active licensed or permitted products in FY 1998.

Serials Tested

Producers presented APHIS with requests for approval to market 18,380 serials of veterinary biologics in FY 1998, of which APHIS withheld 31 for failing to meet Agency requirements. The Agency conducted 3,791 tests on 1,718 of the 11,985 serials eligible for testing.

Regulatory Actions

APHIS conducted 7 investigations of possible violations of program regulations in FY 1998. Twenty-one regulatory actions were taken in FY 1998.

Reagents

To facilitate consistency and quality of testing by biologics manufacturers and other regulatory authorities, 6,539 vials of reagents were shipped. In addition, 6 new tests and reagents were developed.

Center for Veterinary Biologics

After being established in October 1996, the Center for Veterinary Biologics (CVB) has continued its transition. An office facility close to the laboratory in Ames, Iowa, was leased for the Inspection and Compliance (IC) and Licensing and Policy Development (LPD) units. The transfer of LPD functions from Riverdale, MD to Ames, IA has progressed as outlined in the plan previously submitted to and approved by the Department. The completion date for this transition is projected to be October 1999. The LPD Operational Support Section that was included in the move plan to provide headquarters liaison and stronger focus on program policy documentation was also established in Riverdale, MD.

International Trade

The veterinary biologics program continued efforts to reduce trade barriers that limit the sale of veterinary biological products overseas. Program officials continued to meet with representatives of the European and U.S. biologics industries and with regulatory officials from the European Union (EU) to negotiate a Mutual Recognition Agreement (MRA) with the EU concerning the marketing of veterinary biologics. Excellent progress was made in the drafting of an agreement with text that was satisfactory to the negotiating teams. Upon review by the European Commission, however, this document was returned for further modifications. Requested changes have been reviewed and another draft text of an agreement has been negotiated that is acceptable to the negotiating teams. This

modified draft agreement is currently being reviewed by the European Commission.

Interaction with Canadian regulatory officials continued under the Canada-United States Trade Agreement and the North American Free Trade Agreement. Joint inspections were conducted with Canadian regulatory officials and CVB personnel at two facilities in Canada. Meetings were also held in FY 1998 with regulatory officials from Asia, Germany, United Kingdom, China, Brazil, Russia and Australia to facilitate exchange of information and encourage discussion of regulatory issues.

Under the auspices of the International Office of Epizootics, CVB worked with regulators and industry representatives from the EU, Japan, and the Center for Veterinary Medicine in 1996 to form the Veterinary International Cooperation on Harmonization (VICH), which sets priorities for and coordinates the harmonization of regulatory requirements on an international basis. This organization has initiated several projects concerning the harmonization of technical requirements for the registration of veterinary pharmaceutical products; and at the last Steering Committee Meeting in August 1997 established two new working groups to address projects concerning the harmonization of quality test requirements and post licensing monitoring procedures (pharmacovigilance) for veterinary biological products.

In Vitro Potency Testing

In-vitro potency testing of veterinary biologics was emphasized. Guidelines for relative potency assays and reference preparations based on ELISA antigen quantification were published providing further advice in the use of in-vitro potency test procedures for inactivated veterinary biological products. CVB personnel participated in international meetings on in-vitro testing and provided specific reagents for the development of international standards for in-vitro test procedures. CVB participated with industry in collaborative efforts directed toward the development of national references for in-vitro assays for four disease agents that are targets of numerous vaccines. The development of these in-vitro procedures will result in a significant reduction in the use of animals in the testing and production of veterinary biological products.

Testing of Master Seeds

In FY 1998, APHIS tested 7 genetically engineered master seeds. These included bacterial gene-deleted agents, viral vectors, and recombinant expressed proteins. A pilot vaccinia-vectored swine influenza vaccine was designed and tested for immunogenicity and safety to enhance program expertise in molecular vaccinology techniques. Requirements for naked DNA vaccines were discussed within the program, with other regulators, and with firms proposing such products. A one-day naked DNA workshop was held in conjunction with the Veterinary Biologics Public Meeting.

Quality Assurance

The Quality Assurance (QA) initiative with the National Veterinary Services Laboratories continued this fiscal year. Progress was made in establishing an internationally recognized laboratory QA program for standardizing internal processes and methods, instrument calibration, data reporting and tracking systems, and auditing and validation practices. Several laboratory audits were conducted and formal compliance plans were developed to address all deficiencies. A QA performance standard was established for all laboratory supervisors and other key technical positions.